



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the National Coordinator
for Health Information Technology
Washington, D.C. 20201

August 31, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Upton:

I am writing in response to your letter regarding the Office of the National Coordinator's (ONC) recent notice of proposed rulemaking (Proposed Rule).¹ As you know, the Proposed Rule would modify the ONC Health IT Certification Program (Program) to reflect the widespread adoption of certified electronic health records and the rapid pace of innovation in the health IT market. The comment period for the proposed rule closed on May 2, 2016.

We appreciate the questions raised in your letter. We are carefully considering the comments we received from stakeholders during the comment period. However, as per the deliberative rulemaking process, ONC is limited in the discussion of specific matters related to the consideration or adoption of policies in connection with the Proposed Rule, including agency decisions regarding any changes that may be made to the proposed rule before it is finalized. We look forward to the opportunity to meet with you and your staff once the final rule publishes and we are able to fully discuss these matters.

The health IT landscape is at an exciting inflection point – one where technology, policy, and demand are poised to change the way we think about, access, and use health information. Over the past seven years, the United States has seen a historic transformation as we moved from a primarily paper-based health system, to one where nearly every hospitalization has a digital footprint. Recent data releases have helped quantify just how rapidly technology has transformed hospitals and doctors' offices. In 2008, the year after Apple released the first iPhone, less than one in 10 hospitals had an electronic health record (EHR) system with imaging capabilities. Today, that number has grown to over 84 percent, a nine-fold increase. Nearly all hospitals (96 percent) possess EHRs that satisfy the Program criteria, and close to eight in 10 (78 percent) office-based physicians now use a certified EHR, yet another dramatic increase.

¹ ONC Health IT Certification Program: Enhanced Oversight and Accountability, 81 FR 11056 (proposed March 2, 2016).

In short, a vast amount of electronic health data now exists to inform and support health care that simply did not six years ago. This is already leading to real-world benefits for individuals and clinicians. But the adoption of health IT is just the first step to ensuring health data flows in a way that protects the safety, privacy, and security of patients and their data. As the health IT landscape matures, so too must the Certification Program.

Purpose and Authorities of the Proposed Rule

As stated in the Proposed Rule, the Health Information Technology for Economic and Clinical Health (HITECH) Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and electronic health information exchange. Section 3001(b) of the Public Health Service Act requires that the National Coordinator for Health Information Technology (National Coordinator) perform specified statutory duties (section 3001(c) of the PHSA), including keeping or recognizing a program or programs for the voluntary certification of health information technology (section 3001(c)(5) of the PHSA), in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that, among other things: Ensures that each patient’s health information is secure and protected, in accordance with applicable law; improves health care quality; reduces medical errors; reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information; and promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services (see section 3001(b) of the PHSA).

Consistent with this statutory instruction, the Proposed Rule includes ONC’s role in the Program to encompass the direct review of health IT certified under the Program and address non-conformities found in certified health IT. The Proposed Rule also proposes processes for ONC to directly address testing issues. These processes do not exist today under the current Program structure, in contrast to ONC’s oversight of ONC-ACBs. In addition, the Proposed Rule includes a provision for the increased transparency and availability of identifiable surveillance results. We proposed that the publication of identifiable surveillance results would support further accountability of health IT developers to their customers and users of certified health IT.

Resources related to the proposed rule

Under the Proposed Rule, ONC anticipated that direct review would be relatively infrequent and would focus on situations that pose a risk to public health or safety. An effective response to these situations could require the timely marshaling and deployment of resources and specialized expertise by ONC. It may also require coordination among federal government agencies.

Privacy and Security

The Proposed Rule seeks to increase Program transparency and health IT developer accountability for their certified health IT. As part of this effort, the Proposed Rule would require

ONC-ACBs to publicly publish on their Web sites identifiable surveillance results on a quarterly basis. These surveillance results would include information such as: names of health IT developers; names of products and versions; which certification criteria and Program requirements were surveilled; and the outcomes of surveillance. This information is already collected by ONC-ACBs as part of their surveillance efforts under the Program and should be readily available for posting on their Web sites.

The Proposed Rule underscores that ONC does not propose to require that publicly posted surveillance results include certain information that is proprietary, trade secret, or confidential (e.g., “screenshots” that may include such information). It also states that ONC would expect health IT developers and ONC-ACBs to ensure that such information is not posted when making available the information above.

Direct Review

Consistent with section 3001 of the PHSA, the Proposed Rule would expand ONC’s role in the Program to encompass the ability to directly review health IT certified under the Program. As proposed, this review would be independent of, and could be in addition to, surveillance conducted by ONC-ACBs and would be designed to ensure that concerns within the scope of the Program can be appropriately addressed and that ONC can continue to meet its responsibilities under section 3001 of the PHSA.

We proposed that ONC’s review would complement and be coordinated with the existing surveillance activities of ONC-ACBs. ONC-ACBs have the necessary expertise and capacity to effectively administer certification requirements under a wide variety of circumstances. Nevertheless, based on ONC’s experience administering the Program and on feedback received from ONC-ACBs and the public in comments on the proposed rule for the 2015 Edition certification criteria, we explained that there may be certain instances when ONC review of certified health IT is necessary to ensure continued compliance with Program requirements, but such review is beyond the scope of an ONC-ACB’s responsibilities, expertise (i.e., accreditation), or resources. Accordingly, we proposed that the existing role of ONC-ACBs could be complemented by establishing a process for ONC to directly review certified health IT. We stated that ONC anticipated that such review would be relatively infrequent and would focus on the situations that pose a risk to public health or safety or that present unique challenges or issues that ONC-ACBs may be unable to effectively address.

The Proposed Rule emphasizes that the direct review processes described above would promote health IT developers’ accountability for the performance, reliability, and safety of certified health IT and facilitate the use of safer and reliable health IT by health care providers and patients. Specifically, ONC’s direct review of certified health IT would permit ONC to assess non-conformities and prescribe comprehensive corrective actions for health IT developers to address them, including notifying affected customers. As the Proposed Rule stated, ONC’s first and foremost goal would be to work with health IT developers to remedy any non-conformities with certified health IT in a timely manner and across all customers. The Proposed Rule noted that ultimately suspending and/or terminating a certification issued to a Complete EHR or Health IT Module under the proposals would serve to protect the integrity of the

Program and users of health IT. Overall, the proposed direct review processes would support and enable the National Coordinator to fulfill his responsibilities under the HITECH Act, instill public confidence in the Program, and protect public health and safety.

In summary, through the Proposed Rule, ONC proposed to enhance its ability under the HITECH Act to address and correct non-conformities found in certified health IT products and to empower health IT consumers by making more information available about how an individual certified health IT product performs in the field. Again, thank you for your ongoing interest in the work of ONC.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Vindell Washington", with a stylized flourish at the end.

B. Vindell Washington, MD, MHCM
National Coordinator
Office of the National Coordinator for Health Information Technology